Package leaflet: Information for the patient

Deferiprone 500mg film-coated tablets
Deferiprone 1000mg film-coated tablets
deferiprone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.
- A patient card is attached to the leaflet. You should detach, complete, read the patient card carefully and carry it with you. Provide this patient card to your doctor if you develop infection symptoms such as a fever, sore throat or flu-like symptoms.

What is in this leaflet:

1. What Deferiprone tablets are and what they are used for

Deferiprone film-coated tablets (called Deferiprone tablets throughout the rest of this leaflet) contain the active substance deferiprone. Deferiprone is an iron chelator, a type of medicine that removes excess iron from the body.

Deferiprone tablets are used to treat iron overload caused by frequent blood transfusions in patients with thalassaemia major when current chelation therapy is contraindicated or inadequate.

2. What you need to know before you take Deferiprone tablets

Do not take Deferiprone tablets:
- if you are allergic to deferiprone or any of the other ingredients of this medicine (listed in section 6);
- if you have a history of repeated episodes of neutropenia (low white blood cell (neutrophil) count);
- if you have a history of agranulocytosis (very low white blood cell (neutrophil) count);
- if you are currently taking medicines known to cause neutropenia or agranulocytosis (see "Other medicines and Deferiprone tablets");
- if you are pregnant or breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Deferiprone tablets:

- the most serious side effect that may occur while taking deferiprone tablets is a very low white blood cell (neutrophil) count. This condition, known as severe neutropenia or agranulocytosis, has occurred in 1 to 2 out of 100 people who have taken deferiprone in clinical studies. Because white blood cells help to fight infection, a low neutrophil count may place you at risk of developing a serious and potentially life-threatening infection. To monitor for neutropenia, your doctor will ask you to have a blood test (to check your white blood cell count) performed regularly, as frequently as every week, while you are being treated with Deferiprone tablets. It is very important for you to keep all of these appointments. Please refer to the patient card attached to the leaflet. If you get any symptoms of infection such as fever, sore throat or flu-like symptoms, immediately seek medical attention. Your white blood cell count must be checked within 24 hours in order to detect potential agranulocytosis.

- if you are human immunodeficiency virus (HIV) positive or if your liver or kidney function is severely impaired, your doctor may recommend additional tests.

Your doctor will also ask you to come in for tests to monitor body iron load. In addition, he or she might ask you to undergo liver biopsies.

Other medicines and Deferiprone tablets
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Do not take medicines known to cause low white blood cell count (neutropenia) or agranulocytosis (see "Do not take Deferiprone tablets"). Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

Do not take **aluminium-based** antacids at the same time as taking Deferiprone tablets.

Please consult with your doctor or pharmacist before taking **Vitamin C** with Deferiprone tablets.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

Deferiprone tablets may cause harm to unborn babies when used by pregnant women. Deferiprone tablets must not be used during pregnancy unless clearly necessary. If you are pregnant or you become pregnant during treatment with Deferiprone tablets, get medical advice immediately.

Both female and male patients are recommended to take special precautions in their sexual activity if there is any possibility for pregnancy to occur: Women of childbearing potential are recommended to use effective contraception during treatment with Deferiprone tablets and for 6 months after the last dose. Men are recommended to use effective contraception during treatment and for 3 months after the last dose. This should be discussed with your doctor.

Do not use Deferiprone tablets if you are breastfeeding. Please refer to the patient card attached to the leaflet.

Driving and using machines
Not relevant.

3. How to take Deferiprone Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults
- The amount of Deferiprone Tablets that you take will depend on your weight. Your doctor will decide how much to give you.
- The usual dose is 25mg/kg, three times per day (to give a total daily dose of 75mg/kg).
- The total daily dose should not exceed 100mg/kg.
- Take your first dose in the morning. Take your second dose midday. Take your third dose in the evening.
- Deferiprone tablets can be taken with or without food; however, you may find it easier to remember to take your medicine if you take it with your meals;
- The 500mg and 1000mg tablets can be divided into equal doses.

Children
There are limited data available on the safety of deferiprone tablets in children. If the doctor decides that your child needs this medicine, they will determine the most appropriate dose to give.

If you take more Deferiprone tablets than you should
There are no reports of acute overdose with Deferiprone tablets. If you have accidentally taken more than the prescribed dose, you should contact your doctor.

If you forget to take Deferiprone tablets
- Deferiprone tablets will be most effective if you do not miss any doses;
- If you do miss one dose take it as soon as you remember and take your next dose at its regularly scheduled time;
- If you miss more than one dose do not take a double dose to make up for forgotten individual doses, just continue with your normal schedule.
- Do not change your daily dose without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most serious side effect of Deferiprone tablets is a very low white blood cell (neutrophil) count. This condition, known as severe neutropenia or agranulocytosis, has occurred in 1 to 2 out of 100 people who have taken deferiprone in clinical studies. A low white blood count can be associated with a serious and potentially life-threatening infection. **Report immediately to your doctor any symptoms of infection such as fever, sore throat or flu-like symptoms**.

Take immediate action if you have the following side effect:

- allergic reactions. Signs of a severe allergic reaction may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**

Other possible side effects:

Very common side effects (may affect more than 1 in 10 people)
- abdominal pain
- nausea (feeling or being sick)
- vomiting
- reddish/brown discoloration of urine

If you experience nausea or vomiting, it may help to take your Deferiprone tablets with some food. Discoloured urine is a very common effect and is not harmful.

Common side effects (may affect up to 1 in 10 people)
- low white blood cell count (agranulocytosis and neutropenia)
- headache
- diarrhoea
- increase in liver enzymes
- fatigue
- increase in appetite

Not known (frequency cannot be estimated from the available data)
- allergic reactions including skin rash or hives

Events of joint pain and swelling ranged from mild pain in one or more joints to severe disability. In most cases, the pain disappeared while patients continued taking Deferiprone tablets .

Neurological disorders (such as tremors, walking disorders, double vision, involuntary muscle contractions, problems with movement coordination) have been reported in children who had been voluntarily prescribed more than double the maximum recommended dose of 100 mg/kg/day for several years and have also been observed in children with standard doses of deferiprone. The children recovered from these symptoms after Deferiprone tablets discontinuation.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Deferiprone tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and blister or label. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

If you have been prescribed Deferiprone tablets in a plastic bottle, you should use the tablets within 70 days, once the bottle has been opened.

If you have been prescribed Deferiprone tablets in a blister strip, and you have a half tablet, you should push this back into the blister pocket, and store the blister strip in the original carton until it is time for your next dose or for a maximum of 48 hours.

Do not use this medicine if you notice any visible signs of deterioration of the blister pack or the tablets. Return it to your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Deferiprone tablets contains
- The active substance is deferiprone.
- Each Deferiprone 500mg film-coated tablet contains 500mg deferiprone.
- Each Deferiprone 1000mg film-coated tablet contains 1000mg deferiprone.
- The other ingredients are (maize) starch pregelatinised (partially), magnesium stearate, hypromellose, hydroxypropylcellulose, titanium dioxide and macrogol 6000

What Deferiprone tablets looks like and contents of the pack
Deferiprone 500mg tablets are white to off-white film-coated tablets with a score line on one side and plain on the other. Tablets can be divided into equal halves.

Deferiprone 500mg tablets may be supplied in blister packs or plastic bottles of 100 tablets.

Deferiprone 1000mg tablets are white to off-white film-coated tablets with a score line on one side and plain on the other. Tablets can be divided into equal halves.

Deferiprone 1000mg tablets may be supplied in blister packs of 50 tablets or plastic bottles of 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mercury Pharmaceuticals Ltd,
Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom.

Manufacturer
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For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

This leaflet was last revised in June 2024.

PATIENT/CARER REMINDER CARD

((Front Cover))	((Back Cover))
Important Safety Reminders for Patients taking Deferiprone tablets **Prescribing doctor:** **Phone No:**	**FOR WOMEN OF CHILDBEARING AGE** Do not take Deferiprone tablets if you are pregnant or if you are trying to become pregnant. If taken during pregnancy, Deferiprone tablets may seriously harm the unborn baby. You must use effective contraception while you are taking Deferiprone tablets. Ask your doctor which method is best for you. If you become pregnant while taking Deferiprone Tablets, stop taking the medicine immediately and tell the doctor. Do not take Deferiprone tablets if you are breastfeeding.
((**Inside 1**)) **MONITORING YOUR WHITE BLOOD CELL COUNT WITH DEFERIPRONE TABLETS** There is a small chance that you may develop agranulocytosis (very low white blood cell count) while taking Deferiprone tablets, which may lead to a serious infection. Even though agranulocytosis only affects 1 to 2 out of 100 users, it is important to monitor your blood on a regular basis.	((**Inside 2**)) Make sure you do the following: 1. Have your blood monitored on a weekly basis. 2. Contact your doctor immediately if you develop a fever, sore throat or flu-like symptoms.